

Similar Risks – Different Results

Analyzing the Inconsistent Application of the
Precautionary Principle in European GMO
Authorization

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1. Introduction

“Sometimes it is much better to be safe than sorry” (Sunstein, 2003, p.1019). This proverb represents the essence of the precautionary principle (PP), which became salient in Western German environmental policy during the late 1970s, when policy-makers saw the explicit need for a so-called *Vorsorgeprinzip* for the first time (Fischer, Jones & von Schomberg, 2006, pp.2- 3). Nowadays, the PP is widely used in national, as well as international law, yet also heavily criticized. The principle legitimizes to take actions in situations of scientific uncertainty,¹ in which risks and their respective probabilities are unknown. Some academics claim that the PP is a no-risk- and non-science based principle (see e.g. Fischer, Jones & von Schomberg, 2006; Haritz, 2010; Rogers, 2001; Victor, 2001; Zander, 2010). It is often even deemed as a “paralyzing” principle (Sunstein, p.1004) that leads to overregulation (Löfstedt, 2004) and encourages regulators to only focus on one risk while forgetting that we live in the “real world of multiple risks” (Wiener and Rogers, 2002, p.322). Nevertheless, by many this principle is esteemed as providing safer regulation, arguing that criticism should rather be directed at its implementation and operation in practice (Fischer, Jones & von Schomberg, 2006).

In the European Union (EU) the use of the PP has been described as leading to inconsistent and arbitrary decision-making by academics (Zander, 2010), industry (Monsanto, 2011) and policy-makers (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz [BMELV], 2011). According to Zander, “similar situations are not treated in a comparable fashion, which makes it increasingly difficult to foresee how and when precautionary measures will be applied” (p.327). Consequently, there is a risk of unfair and incoherent regulation, impeding further Research and Development (R&D) and preventing citizens from being properly protected against real risks. Furthermore, the arbitrary use of the PP by certain Member States (MS) leads to distortions in the internal market (Zander, 2010).

Due to the public’s distrust of science and governmental regulation of food and feed resulting from the BSE crisis (Victor, 2001), the PP has become highly important for regulation of genetically modified organisms (GMOs) in the EU. Particularly in the field of GMO authorization, the use of the PP in the EU has been frequently criticized for its incoherence and lack of transparency (Wiener and Rogers, 2002; Zander, 2010). Accordingly, an in-depth analysis of example authorization procedures can give insights in how to improve the PP’s application in practice.

¹ It should be noticed that science can never provide absolute certainty (see e.g. Zander, 2010).

Since this can only be realized within an improved procedural framework, this article seeks to further develop the so-called “procedural precautionary principle” (see e.g. Fischer, Jones & von Schomberg, 2006; Haritz, 2010; Zander, 2010) by creating a ‘tool-box’ for the analysis of the PP in practice. This tool-box will be applied to the analysis of the authorization procedures for cultivation of MON810 and Bt11 in the EU. While both GMOs contain the same Bt-protein, the policy outcomes of these two authorization procedures were quite different. MON810 was approved for cultivation in the EU, whereas the authorization procedure of Bt11 is currently stalled. The question thus arises why in two cases of similar situations of uncertainty, the policy outcomes varied considerably. The incoherent application of the PP in the two authorization procedures seems to constitute the problem.

However, the analysis of the respective authorization procedures suggests that the answer to this question goes beyond pointing to inherent flaws of the PP. Rather, the lack of a uniform perception of the PP, and particularly the deficient procedural framework of it in the EU constitute the problem. By presenting two scenarios developed based on the analysis of the case studies of MON810 and Bt11, this article will depict how the authorization procedure for GMOs in the EU could become more coherent, comprehensible and reliable, as well as more effective. This article therefore adds to the current scientific and political debate surrounding the principle by further developing the procedural version of the PP and by designing scenarios which can help to evaluate current regulatory developments and improve the application of the PP in the field of GMOs.

First, the methodology used throughout the analysis will be explained. Second, the PP’s relevance in EU legislation as well as the different versions of the PP will be elaborated on before turning to a procedural PP developed for the analysis of the subsequent case studies. Afterwards, the authorization procedures of MON810 and Bt11 will be examined by means of the procedural PP. Based on this analysis two scenarios on the future use of the PP in the EU authorization procedure for GMOs will be presented. Lastly, a short conclusion will sum up the findings of this article.

2. Methodology

The main question this article seeks to answer is *why*, facing virtually the same situation of scientific uncertainty, the authorization procedures for cultivation of Bt11 and MON810 have taken such different paths. In the course of this article, the focus will be largely on *how* the PP has been applied in the relevant cases and whether this influenced or even caused incoherent decision-making.

Founded on an extensive literature review on various perceptions of the PP, the theoretical framework will be based on the three different versions of the principle suggested by Wiener & Rogers (2002, pp.320-1). However, due to the difficulty of identifying these neatly subdivided versions of the PP within the complexity of the EU multi-actor framework, this article complements Wiener & Rogers' approach with a practical, application-based view of the precautionary principle² – a procedural PP – which allows pinpointing the exact differences in how the PP was applied, by breaking the principle down into several smaller features. Moreover, this conceptual framework will also serve as a 'tool-box' to 'build' future scenarios, proposing how to avoid similar situations in future.

The choice of methodology that one uses for research largely depends on the research questions that are asked (Berry, 2002, p.673). While every type of research method has its specific qualities, "case studies are the preferred strategy when 'how' or 'why' questions are being posed" (Yin, 2009, p.1). Additionally, Yin states that case-studies are generally the best choice if the researcher cannot control the events being studied, and when the subject of study is a 'contemporary phenomenon with some real-life context' (ibid.). Moreover, all types of evidence, such as documents, interviews, observations etc. can be included in the study (p.8), which is why Yin refers to the case study as an "all-encompassing" and "comprehensive" research method (p.13).³ The case-study research will be largely based on desk-research techniques, yet to triangulate, this article also employs interviews in order to increase the reliability⁴ of the data used (p.14).

The design of an interview-study can vary greatly and depends on the purpose it functions in the overall study. Aberbach and Rockman (2002) point out that when the goal of an interview study (as it is in this case), is to fill in knowledge gaps or collect specific opinions, it is advisable to select specific subjects for interviewing (p.673). Naturally, when evaluating the findings of interviews, it is crucial to be aware of inherent shortcomings with regards to the reliability, validity and objectivity of the data obtained (Berry, 2002, p.680).

Based on the findings of the case study, two possible future scenarios will be developed. The inclusion of the scenario approach adds to the current scientific repertoire of risk research, as scenarios can be employed to "explain possible futures in a structural way" (Fox et al, 2011, p.38), yet they are currently not applied frequently in the study of riskmanagement and evaluation (van Asselt et al., 2010). Especially in the field of the PP, rarely ever are the suggestions which are brought forward in the academic literature really applied or tested.

2 For more information see: Haritz, 2010.

3 For more information see: Yin, 2009.

4 For more information see: Berry, 2002; Aberbach & Rockman, 2002.

Therefore, in this case, two scenarios will be developed, both serving different purposes. The first scenario is based on an extrapolation of current developments in the area of GMO regulation. This 'Commission scenario' is based on "what will happen if the most likely development unfolds" (Börjeson et al., 2006, p.726). The second scenario will function as an 'alternative' version. It incorporates the findings from the analysis of the application processes and designs a functional procedural version of the PP for the area of GMO risk regulation that can reconcile MS, Commission, stakeholder and WTO concerns.

In short, this approach not only makes it possible to analyze what went wrong in the policy process, but moreover points towards the possible consequences of current reactions to the problems identified, and further develops and applies an alternative solution instead.

3. Precautionary Principle

This section elaborates on the application of the PP in the EU and introduces as well as criticizes different versions of the PP. The intention of this section is not to present an exhaustive overview of the academic debate on the PP, but rather to become familiar with a prudently chosen interpretative framework for the PP's application, relevant to the analysis of the following case studies, as well as to the development of the final scenarios.⁵

3.1 Precautionary Principle in the EU

With the Maastricht Treaty the PP was incorporated into EC law (Fischer, Jones & von Schomberg, p.10). The principle is included in Art. 191(2) TFEU, stipulating that the EU's environmental policy must be based upon the PP, yet without giving any definition of the principle. In 2000, the European Commission published a Communication on the PP (European Commission, 2000) with the intention to make its implementation more coherent (Fischer, 2002, pp.8-9). However, a clear definition of the principle was still not given.

Nevertheless, the Commission stated that it was "wrong to conclude that the absence of a definition has to lead to uncertainty" (European Commission, 2000, p.1). Until now the only attempt to define the PP within the legal framework of the EU can be found in Art.7(1) of Regulation EC/178/2002, commonly known as 'General Food Law', which was created in

5 For an extensive debate on the PP see e.g. Sandin, P. (1999). Dimensions of the Precautionary Principle. *Human and Ecological Risk Assessment*, 5(5), .889-907 and O'Riordan, T., Cameron, J., & Jordan, A. (Eds.). (2001). *Reinterpreting the Precautionary Principle*. London: Cameron May International Law & Policy.

response to the BSE crisis. This clearly shows that the application of the PP is no longer confined to the field of environment but has also found its way into food safety, including GMOs. Furthermore, the PP is a “general principle of Community law”, and hence a legally binding rule in the EU (ECJ, 2002, para.184).

Nevertheless, the WTO’s stringent application of the PP has to be considered too. The diverging interpretations and applications of the principle, particularly in the field of GMOs, have led to trade disputes between the EU and the WTO before. On the WTO level the PP is incorporated into Article 5.7 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (ECJ, 2002, para.184). It is of particular importance that Article 5.7 is read in conjunction with Articles 5.1 and 5.2 of the agreement, as for example, in the EC Biotech case, the WTO Panel ruled that the PP cannot be used to obviate a risk assessment (WTO, 2006).

3.2 The Procedural Precautionary Principle

This section will introduce an interpretative framework to be used in the following analysis of the case studies and in the development of the scenarios. Wiener and Rogers (2002) distinguish between three “versions” of the PP, in ascending order regarding its strictness: 1) “Uncertainty does not justify inaction”, 2) “uncertainty justifies action” and 3) “uncertainty requires shifting the burden and standard of proof.”

The first version of the PP can be found for instance in the Bergen Declaration of 1990. It allows for action, however, it does not give an answer to the question “what action to take, given inevitable uncertainty” (Wiener and Rogers, 2002, pp.320-1). The second version is more aggressive since it does not only imply that there is a “right to act” but also that there is a “duty to act” (Haritz, 2010, p.144). Nevertheless, it does not provide regulators with information on how precautionary action should look like, either. One example of this “proactive version” (ibid.) can be found in the Wingspread Statement of 1998. According to Haritz, the actions taken following from either the first or second version of the PP depend on “the social, economic, cultural and legal settings” and the “respective policy area” where they are taken (p. 138). The third, most aggressive version suggests explicit action. However, its application might lead to overregulation and is seldom used in practice (Wiener and Rogers, p.321). Haritz claims that the definition of the PP in the Third International Conference on the Protection of the North Sea, as well as the use of the PP in the EU come close to this third “risk- minimizing” version (p.144). However, it is arguable whether the PP used in the EU is risk- minimizing or rather proactive and usually varies on a case-by-case basis. The three versions of the PP vary in the degree of action that might be taken in cases of uncertainty. In the following case studies, however, the focus

will be on different perceptions of the threshold levels of uncertainty necessary in order to take precautionary actions. Wiener and Rogers' three versions of the PP are nonetheless very helpful as a theoretical framework for this article, since the degree of an action and the degree of uncertainty are closely entangled, and it is almost impossible to clearly distinguish between those two elements when the PP is applied in practice.

Based on the analysis of Wiener and Rogers' three versions of the PP, Haritz, stresses the need for a procedural PP that would provide a framework for decision making as well as the procedure for invoking the principle, in which the burden of proof would be shared by the regulator and the applicant. This fourth version of the PP would complement one of the three versions of the principle presented above and make its application not only operable but also more democratic (pp.146-9). The need to have a procedural framework for applying the PP has also been stressed by Fischer and Harding (2006). They argue that the application of the PP cannot be solved by a "prescribed formula or quantified algorithm", but only by an institutional structure developing a flexible process adapted to the problem (p.123). Without such a procedural framework, they conclude, the PP's application in the EU seems to be arbitrary. Nevertheless, one has to take into account that different legal cultures provide for different legal frameworks and procedures in different judicial systems (ibid.).

4. A Tool-Box for the Procedural Precautionary Principle

Academic scholars and political working groups have presented many attempts of analyzing the procedural version of the PP by breaking it down into smaller, tangible features that play into how the principle is implemented in the policy-making process (van Dijk et al, 2011; Mbengue & Thomas, 2004; Cheyne, 2006). These findings however tend to be rather narrowly focused on few aspects of the application-process and thus often fail to grasp all facets of the PP in risk management. This article adds to these attempts by structuring the different procedural facets of the PP according to two rather broad poles: the '*narrow*' and the '*open*'. This juxtaposition facilitates the analysis of case studies according to a set of characteristics and allows to subsequently draw conclusions about the pitfalls and inconsistencies that lie at the bottom of the authorization procedures. Moreover, the procedural breakdown of the PP will further serve as a basis

for the scenarios, which are developed later in this article. The debates surrounding the application of the PP in a procedural framework have evolved along five issue areas, which often overlap and are to a large extent interdependent.⁶

4.1 When to apply the Precautionary Principle

The first issue is whether the PP should be regarded as a ‘decision-rule’ or as a ‘strategy’. According to van Dijk et al, using the PP as a strategy “in each step of the [decision-making] process” (2011, p.5), prevents arbitrary regulation in the risk management phase only (2011, p.4). Gardiner, however, has suggested that a ‘purely procedural PP’ offers no directional advice and thus no guidance in decision-making (2006). Adding to this criticism, Cheyne has stated that the risk-evaluation phase is the appropriate situation to employ the PP, hence allowing for a higher degree of objectivity in the phase of scientific assessment and the choice of an adequate policy response (2006, p. 843).

Nonetheless, Motaal has suggested that in practice, it might be impossible to limit the PP to certain phases of the decision-making process, as scientists often already implicitly apply the principle in risk assessment by using ‘inference options’ which prioritize an over- or underestimation of risks (2005, p.495). Therefore, it will also be important to look at how the different phases of risk regulation are connected. While in practice, risk assessment and management are often perceived as separate steps (Cheyne, 2006), van Dijk et al. point out that it is in fact “not a simple linear series of separated steps”, as new issues may arise at any point in decision-making, leading to a back-and-forth process between the stages (p.5).

4.2 Level of Codification

A second source of disagreement, particularly among legal scholars, has been the degree of codification that is needed for an effective application of the PP. On the one hand, it has been claimed that only a precisely defined version can lead to effective and coherent policy-making (Perez, 2006, p.6). On the other hand, scholars have argued that a rather broad interpretation can make the PP better applicable and in fact more effective (Faure & Vos, 2003), suggesting that the former may block scientific progress.

4.3 Basis for the Use of the Precautionary Principle

A third area of controversy has been whether the use of the PP should only be mandated by scientific evidence, or whether it should be politicized. Perez has stressed the “important

⁶ Not all characteristics will be analyzed in the article, but are included here for the sake of developing a comprehensive theoretical framework.

political facets of the precautionary principle”, claiming that science cannot determine the acceptable risk- level for society and that only politics can reconcile scientific, societal and economic pressures (2006, p.17).

This conviction is related to van Dijk et al.’s finding that even recommendations by Scientific Advisory Bodies are “inherently political” (Van Dijk et al., 2011, p.11). Therefore, rather than giving policy recommendations, the authors argue that such bodies should only have the task of “map[ping] the decision situation” by presenting all available evidence and all possible interpretations of the uncertainties, while acknowledging the value-judgments that have played into the respective interpretations (p.12). This would inform decision-makers scientifically, without precluding decisions.

The end of strictly science-based decision-making in turn would allow for an increased participation of stakeholders in the process. Van Dijk et al. point to a demise of traditional technocratic regulatory regimes, as “governments increasingly seek to arrive at policy decisions in consultation with stakeholders” (2011, p.5). The authors are convinced that the inclusion of the stakeholders’ diverse set of expertise can enhance the quality of the decisions, but that such participation would also necessitate strict procedural rules (p.6).

The degree to which stakeholders can take part in the regulatory process also depends on the emphasis that is put on the inclusion of ‘objectivity’ requirements when invoking the PP, such as cost-benefit analyses or proportionality tests (Motaal, 2005, p.485). While proportionality requirements have been applied frequently in WTO-rulings (Cheyne, 2006, p.852) and ECJ case law (Rogers, 2011, p.475), the ECJ has rarely ever mentioned the necessity of cost-benefit analyses, although set out in the 2000 Commission Communication (Rogers, 2011, p.478). On the contrary, by not relying on such ‘objective’ factors, policymakers would have the possibility of including societal concerns in their decisions. Critics believe the inclusion of such concerns would cause the principle to be unreliable and incoherent (Sunstein, 2003). Contrarily, van Dijk et al. have argued that societal input might lead to more acceptable results, by increasing transparency and accountability of decisions (2011, p.6).

Eventually, the role of science also determines the provisional nature of the PP. Rogers (2011) has pointed out that despite its importance for the principle, the temporary status “has had only limited impact on the PP” in the EU (p.479). In practice, any preliminary negative decision often discourages further research and investments in products (p.480). Rogers thus stresses the importance of time-frames and further scientific research on the product in order to support any provisionally taken decision.

4.4 Dealing with Information

It is well established that “scientific evidence itself is not always neutral, determinative or uniform” (Cheyne, 2006, p.838). In the area of risk-regulation there are thus diverging interpretations of scientific facts. Dominant views have often been referred to as ‘majority’ science, while less common interpretations have been termed ‘minority’ science (Motaal, 2005, p.487). While the inclusion of such minority science has been a contentious issue in risk regulation, both, the WTO (Mbengue & Thomas, 2004, p.8) and the EU⁷ have shown the will to allow the use of minority opinions when invoking the PP, as long as they are based on sound scientific evidence.

Additionally, the statement above implies that *all* scientific results are subjective (Cheyne, 2006, p.838). The questions raised due to this erosion of the classical positivist view on science are mostly concerned with the possible added value the inclusion of subjective views into the risk assessment phase (van Dijk et al., 2011, p.6).⁸

4.5 Risk Communication

The issue of communication influences the application of all aforementioned variables, which is why van Dijk et al. refer to it as “the center piece of sensible risk governance” (2011, p.6). Recalling the intended procedural tool-box, a distinction between rather closed (i.e. dialogue between regulators and scientists only) and more open applications of the PP (i.e. communication amongst all stakeholders) can be drawn. More recently, several scholars have advocated the opening up of the risk communication process, arguing that “if the actors shared their knowledge and experience it is self evident that the likelihood of reaching more optimum risk management decisions when faced with uncertain science would be increased” (Rogers, 2011, p.481). This argument is based on the hope that an open information policy could lead to a convergence of views. However, even proponents of such an approach acknowledge that it cannot solve all disputes (ibid.). Especially the communication to the public is a difficult balancing act between creating transparency and assuring public trust and confidence in experts (van Dijk et al., 2011, p.6).

4.6 Two Ends of the Same Spectrum

Based on the multitude of issues revolving around the PP, this article provides a table which classifies these characteristics according to two rather broad poles of application. Both sides do not represent absolute categories, but two ends of the same spectrum of how the

7 See: Art. 38(1), Regulation 178/2001/EC.

8 For more information see: Mbengue & Thomas, 2004; Cheyne, 2006; Van Dijk et al, 2011.

principle can be applied in practice. It is not the aim of this classification to provide a new set of definitions for the PP. Moreover, features from both sides are not necessarily contradictory. In fact, it is likely that any PP version used in practice will combine characteristics of both sides.

INTREPRETATIONS/APPLICATIONS OF THE PP	
WHEN TO APPLY THE PP	
Narrowly interpreted Legal Principle	Flexibly treated Governance Principle
precautionary principle in Risk Management Phase only	precautionary principle as strategy throughout decision making process
Linear Process/Strict procedural rules	Back and forth communication among all involved actors
LEVEL OF CODIFICATION	
Codified in one binding definition	Considered as Customary law, accounting for complexity and flexibility in application
DECISION MAKING	
De-politicized	Politicized
Scientific advisory bodies as de-facto decisionmakers, providing one clear policy-recommendation	Scientific advisory bodies as advisors only, providing all possible interpretations of the scientific data
Inclusion of 'Cost-Benefit', 'Proportionality' and other requirements	No objectivity-requirements
De-facto permanent decision-making	Temporary decision-making (stressing time-limitation and the need for more scientific evidence)
DEALING WITH INFORMATION	
Scientific information only	Subjective information, societal concerns included
Use of Majority scientific opinions only	Recognition of Minority scientific opinions as valid reasons to invoke precautionary principle
COMMUNICATION/STAKEHOLDER INVOLVEMENT	
Policy-makers (Risk Managers) and Scientists (Risk Assessors) only	Involvement of all Stakeholders throughout decision making process
Communication based on stalemate of opposing scientific opinions (no progress, eventual decision in favor of one or the other, often in Court)	Open Communication process in order to develop a common understanding of the risk-scenario

This tool-box intends to provide the procedural PP with analytical substance, thus complementing the rather rigid and theoretical versions developed by Wiener & Rogers. Analyzing the application of the PP based on the aforementioned procedural and practical factors allows the researcher to determine which conceptual versions of the PP were used in the analyzed cases, and pinpoint the pitfalls in the applications of the principle.

5. Precaution in Authorization Procedures of GMOs in the EU

Based on this theoretical framework, the following section analyzes the MON810 and Bt11 application processes and draws conclusions on how the PP has influenced the respective outcomes.⁹

9 Currently, it is possible to file an application for cultivation of GMOs under two different regimes, Regulation 1829/2003/EC and Directive 2001/18/EC, which repealed Directive 90/220/EC. The main aim of both pieces of legislation is to create a standardized authorization procedure for GMOs throughout the EU and provide for greater public confidence in GMO releases due to more transparency (European PPP Expertise Centre, 2009). A detailed description of the concerned procedures goes beyond the scope of this paper and is referred to only when necessary.

5.1 Case Studies

In the following section the application of the PP in the EU will be examined at the example of the authorization procedures of two different GM crops: MON810 and Bt11.¹⁰ Both cases are concerned with ordinary maize which is genetically modified in such a way that it is resistant against certain pests, especially the European corn borer. This is achieved by transferring the *Cry1A(b)* gene from a particular bacterium into the maize by means of genetic engineering. Next to the *Cry1A(b)* gene, Bt11 maize contains another gene which increases the plant's tolerance to a main component of many herbicides. In both cases, the possible resistance of target species against the Bt-toxin and the unintentional effects of this toxin on non-target organisms, particularly larvae of other insects, have been identified as an uncertain risk involved in cultivation (EFSA, 2005). Yet, since 1998, MON810 can be legally cultivated in the EU while the authorization of Bt11 is still pending.

5.1.1 MON810

5.1.1.1 Authorization of MON810

On 24 May 1996, pursuant to Art.5(1) Directive 90/220/EC, Monsanto Europe applied for the authorization for a genetically altered maize called MON810 with the French Competent Authority (Dolezel et al., 2007). The notification was subsequently forwarded to the Commission and the other MS (European Commission, 1998, recital 5). After several MS objected to the intended labeling and monitoring of the crop, the applicant made amendments to its application (recital 6). In line with Art.13(3) of Directive 90/220/EEC, the Commission requested a scientific opinion from the Scientific Committee on Plants (SCP) for advice and comments on the objections of the individual MS to be taken into account. However, it can also be observed that merely policy-makers and scientists had a say in the process, whereas other stakeholders, such as environmental organizations were not involved directly.

In its opinion the SCP concluded that there is “no evidence to indicate that the seeds of [this] insect-resistant maize [...] when grown, imported and processed in the manner indicated, are likely to cause adverse effects on human or animal health and the environment” (SCP, 1998). Furthermore, the SCP stressed the fact that the Bt-toxin produced by MON810 had been used as an agricultural pesticide against certain

¹⁰ This article focuses on the authorization for the cultivation of GMOs in the EU. The authorization for GMOs as or in food and food products, feed and feed products as well as the use of GMOs for any other purpose will not be touched upon.

larvae widely across the EU for more than 20 years (ibid.). It went on to state that “the development of resistance in injurious target pests will be delayed by the rigorous adoption of a comprehensive resistance management strategy” (ibid.), in particular stringent monitoring rules. Although a risk concerning cultivation of MON810 was identified, the SCP stated that this risk would be sufficiently mitigated (ibid.). Shortly afterwards, MON810 was authorized throughout the EU on the basis of this SCP report. This shows that the scientific body, i.e. the SCP, was trusted enough to convince the policy-makers of their recommendation. Hence, the SCP can be seen as the *de facto* decision maker in this particular process.

5.1.1.2 *Renewal of the Authorization for MON810*

After Regulation 1829/2003/EC had entered into force, MON810 was duly notified to the Commission by Monsanto on 12 July 2004 as existing products in accordance with Art.8(1) and Art.20(1) of Regulation 1829/2003/EC (European Commission, 2011, a). Hence, in 2007 Monsanto Europe applied for renewal of authorization for the use of MON810 for food and feed products, import and processing, as well as for the cultivation of MON810 in the EU under Regulation 1829/2003/EC (Monsanto, 2007).

Currently, the renewal of authorization for cultivation and all other uses of MON810 is still pending (European Commission, 2011, b). Although the original authorization expired in 2008, according to Art.23(4) of Regulation 1829/2003/EC, MON810 may still be placed on the market, and thereby also cultivated, until an official decision in the matter has been taken. EFSA has already given an opinion on the case at hand (EFSA, 2009) and has forwarded it to the Commission, the MS and the applicant in conformity with Art.18(6) Regulation 1829/2003/EC, but still no decision has been taken.

EFSA's scientific opinion describes MON810 to be “as safe as its conventional counterpart with respect to potential effects on human and animal health” (EFSA, 2009, p.56). Furthermore, EFSA stressed the fact that the *Cry1A(b)* had been extensively assessed in previous opinions of the EFSA GMO Panel and that it has continuously been found to be safe (p.23). In its opinion, EFSA thoroughly responds to concerns regarding the adverse effects MON810 could have on various non-target organisms and repeatedly comes to the conclusion that this GM crop is unlikely to have adverse effects on various non-target organisms (pp.2748). However, in the case of non-targeted lepidopteran larvae EFSA admitted that more data would be required to rule out uncertainties which are inherent in any ecological modeling exercise (p.37). It continued to advise to accompany the adoption of the cultivation of MON810 by stringent management measures. Regarding the development of target organism resistance, EFSA estimated that “no significant risk

has been identified in the environmental risk assessment with the exception of resistance evolution in lepidopteran target pests” (p.50). EFSA therefore recommended that the development of resistance in lepidopteran target pests to be persistently monitored so that potential changes are detected promptly (p.54).

5.1.1.3 National Bans and Safeguard Clauses

Once a GMO product has been authorized under the appropriate legislation, it may circulate freely within the EU without MS being allowed to hinder it. This is guaranteed by Art.22 Directive 2001/18/EC. Nonetheless, Art.23(1) Directive 2001/18 provides MS with a safeguard clause, entailing the possibility to temporarily restrict the use of certain already authorized GM products if there are justifiable reasons to believe that they constitute a risk to human health or to the environment. While the emergency clause under Art.34 of Regulation 1829/2003/EC allows for legitimate factors *other than science* to be taken into account, this does not apply to the safeguard clause under Directive 2001/18/EC. When invoking this article, only new or additional *scientific* information made available after the authorization may be considered.

Until now, several MS have invoked the safeguard clause in order to restrict or prohibit the cultivation of GMOs. Currently MON810 is banned from being cultivated in Austria, Greece, Hungary, France, Luxembourg, Germany and Bulgaria. Several MS base their justification to invoke the safeguard clause on claims that MON810 negatively affects nontarget species and facilitates the development of resistance in target species. Yet, the SCP and later EFSA re-emphasized that there are no scientific reasons to think that MON810 would adversely affect health or the environment (EFSA, 2006, p.9). Furthermore, EFSA emphasized several times that the scientific evidence presented by the MS could not be considered as new or consisting of additional information. Despite the Commission’s request to lift these national bans, many of them still remain in place due to the lack of support in the Council. Through this analysis, it becomes clear that the thresholds for taking precautionary measures are set differently by the MS and EFSA, which in turn leads to MS questioning the risk assessments made by EFSA and reduces trust in this scientific body by the MS.

Not only on EU level did these national bans cause controversies, but also on the WTO level. In 2003 the US, Canada and Argentina started proceedings against a number of MS as well as the Commission, criticizing not only the alleged moratorium¹¹ on GMO

11 “[A] general de facto moratorium on approvals was in effect in the European Communities between June 1999 and August 2003” (WTO Report, 2006, p.760). For more information see Prevost, D. (2007). Opening Pandora’s Box: The Panel’s Findings in the EC-Biotech Products Dispute. *Legal Issues of Economic Integration*, 34(1), 67101.

authorizations but also the national bans by several MS on specific GM products (WTO, 2006, para.2.1). The WTO Panel came to the conclusion that the national safeguard measures did not comply with the SPS Agreement. It was assessed that these measures fell outside the scope of Art.5.7 of the agreement, as this provision can only be invoked if the relevant scientific evidence is insufficient. However, the opinions issued by the SCP and EFSA were recognized as being valid risk assessments for the purpose of the WTO and stated that scientific evidence was sufficient. Nevertheless, the scientific evidence presented by the MS to justify their safeguard measures could not be qualified as a valid risk assessment as required under Art.5.1 of the SPS Agreement.¹² Therefore, the WTO Panel came to the conclusion that the national safeguard measures were not in compliance with Art.5.1 and that the MS in question breached their obligations of the agreement.

Besides political and legal consequences, safeguard clauses also have economic implications for the applicant in question as was expressed by Monsanto, Belgium (Monsanto, 2011). First, producers of GM seeds lose the markets in those MS that decide to ban cultivation. Secondly, the invocation of safeguard clauses based on scientific uncertainty also impacts the sales in third countries by giving the product a negative connotation. These issues clearly point towards the necessity of consistent policy making for GMOs, which is emphasized by the following case study on Bt11.

5.1.2 Bt11

In 2003 Syngenta applied for authorization for cultivation of Bt11 with the French Competent Authority in France, which duly forwarded its favorable opinion to the Commission on 16 June 2003 (EFSA, 2005, p.4) and the other MS. Questions and concerns raised by the other MS revolved around the increase in resistance in target pests as well as the negative effects of the toxin on non-target species (EFSA, 2005, pp.5-23). The Commission hence asked EFSA for its scientific opinion, which was published on 20 April 2005 and addressed all concerns forwarded by the MS. The possible development of resistance to Bt-toxin in target pests was identified as a possible but low risk and EFSA supported the monitoring plan¹³ to control these unwanted effects. Furthermore, “appropriate risk management strategies” (EFSA, 2005, p.24) were suggested to be taken in order to minimize effects on non-target insects, although EFSA also stated that the actual possibility of such effect was “foreseen to be very low” (EFSA, 2005, p.20). Overall the EFSA GMO Panel concluded that “there is no evidence to

12 The requirements for a valid risk assessment are laid out in paragraph 4 of Annex A of the SPS Agreement.

13 Such monitoring plans are required according to Art.20 (1) of Directive 2001/18/EC.

indicate that placing of maize line Bt11 and derived products on the market is likely to cause adverse effects on human or animal health or the environment” (EFSA, 2005, p.24).

The scientific opinion depicts the development of resistance in target pests as possible, but still concludes that cultivation of Bt11 does not endanger human and animal health or the environment. The low prioritization of this possible effect suggests an implicit cost-benefit analysis, which prioritizes the benefits of cultivation over the possible adverse long term effects of Bt-toxins. Thus, (non-)precautionary rationales also have a real impact on the risk analysis and a cost-benefit analysis can lead to the downgrading of a certain risk and can therefore “itself determine the outcome of a risk assessment” (Motaal, 2005, p.495).

After EFSA’s scientific opinion, the authorization procedure for Bt11 took a rather unusual turn. Instead of issuing an opinion, the Commission held a technical meeting with MS and EFSA representatives to “discuss the notifications pending under Directive 2001/18/EC (EC, 2001) and including cultivation purposes” (EFSA, 2006, p.1). It enabled the MS to further articulate their concerns about the cultivation of GMOs like Bt11 and also to express their discontent about the EFSA report. As a result, EFSA was requested to further elaborate on certain issues, particularly on the unanticipated effect of the Bt-toxin on non-target lepidopteran species and on appropriate monitoring plans.

Subsequently, EFSA published the requested Annex to its scientific opinion in which it reaffirmed its position towards the effect of Bt11 on health and the environment (EFSA, 2006, p.7). Thus, during a time span of two years the GMO Panel of EFSA had confirmed the safety of Bt11 for cultivation twice.

The technical meeting revealed that MS were apparently not willing to fully trust the first risk assessment carried out by EFSA and demanded further elaborations. Arguably, the issues that were chosen by the MS for further assessment were those which were handled with a relatively high level of precaution on the respective national levels. However, the GMO Panel’s Annex possibly bears witness that EFSA did not recognize the apparent gap between its own precautionary threshold and the one desired by MS and therefore did not to move away from its previous assessment.

5.1.2.1 *Parallel Developments*

Reviewing the past authorization procedures of GMOs in the EU, the Commission published an Action Plan in 2006. The idea behind this was to introduce “practical improvements [that] could be made to the system to improve the scientific consistency and transparency for Decisions on GMOs and develop consensus between all interested parties” (European Commission, 2006). Thereupon, EFSA held a Scientific Colloquium,

concluding that more information was necessary to generate guidelines on how to assess potential risks of GMOs on non-target organisms. EFSA thus started a project titled *Cry proteins and their expression in micro organisms and genetically modified plants* (European Commission, 2007, recital 12). This project was meant “to provide EFSA with a review of all appropriate scientific data on Bt-proteins that are relevant for the risk assessment of GM plants expressing such proteins” (ibid.). Most importantly, however, the assignment was also supposed to include an overview of areas that have not been researched yet, thereby guiding and coordinating future research. Although this first serious attempt to base the use of the PP on a fully developed scientific review, including minority and majority decisions would have helped to combat the apparent lack of trust among MS in EFSA’s scientific assessments, the project was never completed (EFSA, 2011, a).

5.1.2.2 The Commission Proposal to ban Cultivation of Bt11

In 2007 the Commission drafted a Decision to ban the cultivation of Bt11. It featured the findings of eleven scientific studies emphasizing the scientific uncertainty surrounding the effects of Bt11 on non-target organisms (European Commission, 2007, recital 14) and concluded that it was evidently still possible to identify uncertainty concerning the cultivation of Bt11. The risks involved were said to have potentially far-reaching and even irreversible consequences and would render management measures as proposed by EFSA ineffective and inappropriate (recital 21). In the draft explicitly the Commission argues that considering the level of uncertainty still surrounding potential effects on non-target lepidopteran insects, it is impossible to approve the cultivation of Bt11 without disregarding the PP. This argument implies that the threshold of precaution applied by EFSA was clearly not high enough to satisfy apprehensions of opposing MS. Nevertheless, this ban was never adopted.

After the Draft Decision had been published, EFSA was requested to assess the eleven scientific studies and thereby include minority scientific views. In October 2008 EFSA published its opinion on the ‘new’ scientific evidence, which disagrees with the Commission’s assessment that these studies constituted “serious indications” (recital 21) of Bt11’s high risk of adverse effects on non-target organisms. The scientific evidence referred to by the Commission in its Draft Decision is described as “not [providing] new information that would change previous environmental risk assessments” (EFSA, 2008, p.21). EFSA therefore “reaffirm[ed] its previous conclusions on the environmental safety of maize Bt11” (ibid.). This last assessment emphasizes the gravity of the deadlock of diverging risk thresholds of precaution in the authorization procedure.

Although compared to MON810 a more open strategy of communication and multiple risk assessments was employed with Bt11, the authorization has still not been completed.

A higher degree of openness, including back and forth discussion about possible dangers of cultivation of Bt11 between the MS and EFSA, did not lead to an agreement between the two. Moreover, not all MS were willing to support a complete ban for cultivation either, as has been shown by the failure of the Regulatory Committee to adopt an opinion on the Draft Decision. Although a deadlock could be interpreted as a temporarily satisfying situation for MS that oppose the cultivation of Bt11, considering the WTO's stance towards such delays, the situation is unlikely to stay unresolved.

5.2 The Problem Inherent to the Authorization Procedure of GMOs in the EU

The cases studies were initially chosen due to the seemingly inconsistent and arbitrary application of the PP resulting in the different outcomes of both cases in spite of the striking similarities. However, it soon appeared that the reason for inconsistent policy outcomes of the authorization processes of MON810 and Bt11 is not to be found in an inherent arbitrariness of the PP. Nor was it an inconsistent application of the PP by the same actors that has led to the approval of cultivation in one case, and a deadlock situation in the other. Moreover, the slightly diverging, yet still very similar legal frameworks for the initial authorization of both products can also not solely account for the regulatory incoherence, since both frameworks to some degree provide room for precautionary action.¹⁴

Rather, the technical meeting and the subsequent second request to EFSA suggest that the authorization procedure of Bt11 depicts an alternative strategy employed by the MS to handle the situation of cultivation of GMOs. Invoking safeguard clauses had proven to be an ineffective way to prevent cultivation due to the rejection by the Commission, based on the lack of new scientific evidence provided by the respective MS and their failure to comply with WTO rules. Therefore, it is possible to argue that for Bt11, those MS that opposed the idea of cultivating the GMO tried to opt for a more open and communicative risk assessment procedure. Altogether, by improving the communication process between all decision-makers, a less linear application of the PP was used. Admittedly, the intention of the second request to EFSA might have been a genuine desire by the MS to include all available scientific information and possibly to create consensus. Nonetheless, it already suggested a different prioritization of risks used by the MS and EFSA, as expressed by the MS' request to EFSA to elaborate on issues that already had been assessed. Still, this strategy of back and forth communication proved not to lead to a decision acceptable for all actors, either. Since both strategies have failed to deliver adequate regulatory results,

14 Directive 90/220/EEC only demands that attention is given to "precautions related to the safe use of the product" (Art.12), whereas Directive 2001/18/EC explicitly mentions the PP.

the Commission currently plans to amend Directive 2001/18/EC¹⁵ leaving more leeway to MS in the area of GMO cultivation.¹⁶

The analysis of both risk assessments therefore suggests that the main problem of coherent authorization can be found in a difference in thresholds of precaution applied by the opposing MS and EFSA.¹⁷ The authorization procedure for GMOs (in particular the risk assessment) has to shoulder the pressure of reconciling up to 27 different societal perceptions of risk and appropriate levels of precaution, and to allow the decision to be incorporated into 27 different national legal cultures. In both authorization procedures the MS and EFSA agreed on the possibility of such undesired effects of non-target insects, yet their evaluation differed. This constitutes the actual problem.

As a result, the authorization procedures of GMOs in the EU have to be considered rather incoherent and unpredictable. This in itself is fairly undesirable, as it defeats the purpose of regulation on a European level. Moreover though, applicants are likely to be unsatisfied not only with the diverging policy-outcomes, but also with the procedural unpredictability of the current system, which makes it difficult to organize and adjust investments and R&D (Monsanto, 2011). Therefore, it is easy to see that there is room for improvement in the field of GMO authorization.

6. Scenarios

When developing scenarios, it is important to emphasize that there is 'no correct scenario definition or approach', but that they can be applied in a rather flexible manner, tailored to the needs of the researcher (van Notten et al, 2003, p.424). In fact, scenarios and future studies are usually a mix of several methodologies and types of scenarios (Robinson, 2003). Due to this flexibility, the approach makes it possible to develop two different scenarios, one extrapolating from current developments (Commission scenario) and one addressing the problem identified in the case studies (FRAD scenario). By doing this, this article intends, on the one hand, to illustrate the likely consequences of current developments,

15 Mr. Koehler from the BMELV suggested that the Commission currently stalls the authorization procedures to wait for these reforms.

16 This proposal by the Commission is discussed in the following chapter.

17 Mr. Kohler from the BMELV explained this difference in precaution as partly stemming from backgrounds of the experts working in the EFSA Panel as scientists working with GMOs for several years are more comfortable with the idea of GMOs and also more convinced of the safety.

and on the other, to depict how a working procedural PP can be incorporated into the regulatory process for GMOs in the EU. The techniques that will be applied in the following are qualitative, as this allows a more thorough examination of possible consequences, perceptions of the PP, and Member States reactions.

Despite all suggestions about probabilities, one must always keep in mind that scenarios are “not a tool to predict the future”, but a method that provides actors with insights into possible future consequences of existing uncertainties (Fox et al, 2011, p.32), which is why they can be of high relevance for policy makers, stakeholders, policy analysts and other interested parties (ibid.).

6.1 Commission Scenario

Considering the above-mentioned case studies, one can conclude that certain MS are not willing to cultivate GMOs on their territory and have in the past used different strategies in order to resist cultivation, none of which have been proven to be very effective in the long run. The MON810 case has shown that safeguard clauses cannot be seen as a suitable tool to permanently ban the cultivation of GMOs. The Commission has repeatedly requested the respective countries to lift these bans and also the WTO Dispute Panel has declared these national bans illegal since they cannot be justified by valid risk assessments (WTO, 2006). Also, the strategy applied in the authorization process of Bt11 does not offer a worthy alternative, since stalling the process altogether can also be seen as a violation of WTO laws, as it leads to undue delays in the authorization procedure, which was highlighted by the WTO Dispute Panel in the EC Biotech case (WTO, 2006). Looking at it from the EU level, one must also highlight that if a decision-making procedure loses its capability to produce effective decisions, it is likely to be flawed.

As a result of growing pressures by certain MS¹⁸ the Commission submitted a proposal for a regulation to the Council, which is to amend Directive 2001/18/EC.¹⁹ This new provision gives MS the freedom to restrict or even prohibit the cultivation of GMOs on their territory on grounds other than health or the environment. From the point of view of opposing MS, the proposed amendment seems to be quite an attractive solution to the current GMO cultivation issue, as it would allow decisions concerning GMO cultivation to be taken at national or even regional level.

Such decisions could consider certain particularities and different perceptions on

18 After the Council rejected the Commission's proposal requesting Austria and Hungary to lift their bans in March 2003, 13 other MS requested the Commission to draft a legislative proposal, granting more freedom to Member States when it comes to the cultivation of GM crops in the EU.

19 Proposal to insert Art.26(b) (Cultivation) of Directive 2001/18/EC as proposed in COM (2010) 375 final.

the precautionary thresholds of that area. Moreover, justifications for bans need no longer to be scientific, thus implying more flexibility for the MS in the matter (European Commission, 2010, p.3). With this new provision, the Commission hopes to decrease the MS' use of the safeguard clauses, speed up procedures and reduce the institutional burdens on the Commission as well as on EFSA (p.4). These burdens arise due to the consistent objections by MS to opinions and reports of both institutions. Moreover, the Commission is convinced that this new provision will benefit affected stakeholders by providing more clarity about cultivation of GMOs and by rendering the decision-making process more predictable (ibid.). In short, the proposed amendment to Directive 2001/18/EC seems very attractive in the short run since it appears to cater to the interests of all parties involved, seemingly addresses the issue of diverging thresholds, and also because its effect is quite easily achievable. However, when examining the proposed amendment more closely, one will discover that in the end the newly won freedom is in fact rather limited as MS will have to adhere to EU, as well as to WTO law.

First and foremost, the possibility to invoke safeguard clauses based on the proposed amendment is still not likely to comply with WTO law.²⁰ Second, the rationale behind this approach is questionable. Instead of improving the enforcement of current EU law, the Commission now seems to change the law which was violated, thereby rewarding those that breached it in the first place (BMELV, 2011). Thirdly, the measure does not address the initial criticism of the PP, as it does not create procedural coherence or certitude for all involved stakeholders, regarding the principle's procedural application. In fact, shifting the application back to the MS level eradicates all efficiency gains which constituted the initial reason for a European application procedure, thereby constituting a step backwards in the process of European integration. Such a reversal of the European integration process must be seen with caution, not only due to possible implications for the internal market, but also with regards to growing Euro-skepticism in many MS. Consequently, it is intelligible to develop an alternative scenario which seeks to overcome the procedural problems of the PP on a European level.

6.2 Full Risk Assessment Dossier (FRAD) Scenario

The case studies above have revealed that the issue at hand mainly lies with the different threshold levels of precaution inherent in the different risk perceptions applied in the procedure by the MS and EFSA. In order to make the authorization procedure of GMOs in

20 A detailed discussion of compliance with WTO-law when invoking safeguard clauses solely against cultivation unfortunately goes beyond the scope of this paper.

the EU more coherent and effective, while still ensuring flexibility for MS, it is necessary to approximate the different threshold levels of precaution. Naturally, this common threshold level should not equal the one of the MS with the highest threshold, since this could easily lead to a zero-risk strategy which in turn could result in overregulation. Rather, the MS and EFSA need to meet half way; EFSA has to acknowledge that certain MS have a higher level of precaution, whereas the MS have to rekindle their trust in EFSA's risk assessments. A higher level of trust in EFSA would mean that MS would more easily approve of a risk assessment with a lower precautionary threshold than their initial national threshold.

To increase trust while maintaining the current science-based authorization system for GMOs on the European level, this scenario proposes the creation of mandatory Full Risk Assessment Dossiers (FRADs)²¹ by EFSA, on which every European and national precautionary measure has to be based. Although the EFSA reports should continue to contain non-binding recommendations, there is a need for more transparency, as well as traceability of its reasoning. Hence, a scientific opinion by EFSA should provide all the possible interpretations of scientific data available, including minority scientific views to increase its credibility. Most importantly, EFSA has to make all (non-)applications of the PP very clear, such as whether it took into account a cost-benefit analysis or proportionality requirements in their evaluation of the product's overall risk. In short, all implicit applications of precaution need to be made explicit.

A FRAD could be characterized as the centralization of scientific knowledge, a review of all relevant scientific research and related risk assessments brought together by EFSA. Such a review would include a clear identification of areas of uncertainty, which have not been researched yet. Any stakeholder could forward their scientific findings to EFSA, which would in turn provide a comprehensive overview of the scientific state of affairs. In order to ensure compliance with WTO law, only risk assessments in conformity with Art.5(1) SPS Agreement will be accepted by EFSA for this compilation. During the process of data collection, EFSA must refrain from any explicit or implicit (non-)application of precaution. This phase should only focus on the scientific quality of the data that is to be included in the FRAD. Moreover, the FRAD is to be updated annually as to ensure the actuality of the review.

The possibility of invoking a safeguard clause should nevertheless still be available to cater to the needs of MS with unusual high precautionary thresholds and to provide fewer incentives for MS to block the whole authorization process. When invoking a safeguard clause, the respective MS would always have to justify its measure based on one of the

21 The idea of the FRAD is built on the uncompleted EFSA project *Cry proteins and their expression in microorganisms and genetically modified plants* mentioned in Chapter 5.2.2 of this article.

scientific risk assessments contained in the FRAD. By doing so, non-compliance with WTO law would be avoided and minority as well as majority science could be taken into account, as long as there is a valid risk assessment. Since the FRAD would be updated regularly, the question whether a piece of scientific information is 'new' or 'additional' would not arise, as the MS could rely on the FRAD. Therefore, a FRAD means to play a game with open hands, thereby achieving greater certainty for MS and other stakeholders concerning the process of authorization. Moreover, it would prevent the abuse of safeguard clauses.

It is needless to say that different versions of the PP as proposed by Wiener and Rogers will continue to exist. Particularly in situations where the opinions on precaution are too divergent, it will be more difficult to find a compromise on a common threshold level of precaution. However, this problem is inherent in the multi-level governance structure of the EU which always necessitates a political dimension to the decision-making process (BMELV, 2011). By introducing the compulsory use of a FRAD, a certain degree of certainty would be established which in turn would reestablish trust in EFSA. This would allow for an approximation of levels of precautionary thresholds with the possibility for MS with high thresholds to nevertheless legally invoke temporary safeguard clauses. Through the codification of the handling of scientific knowledge in the EU an appropriate application of precautionary measures will be ensured.

7. Conclusion

Recalling the initial starting point of this case study, namely the question as to why in two cases of similar scientific uncertainty the policy outcomes varied considerably, this paper has to conclude that any explanation has to go beyond criticizing an inherent incoherence or arbitrariness of the PP. It has been shown that the immediate reasons for the diverging authorization processes of the two GMOs in question are to be found in how the PP has been incorporated into the procedural framework of the EU and the strategies applied by some MS in order to achieve their objective of resisting cultivation of GMOs. After the first strategy of employing safeguard clauses for MON810 had been unsuccessful, concerned MS reacted by employing a different strategy in the case of Bt11, which in the end led to a standstill of the decision-making process altogether. These strategies were motivated by an underlying rationale of the diverging thresholds of precaution employed by MS, the Commission and EFSA respectively. Therefore, the inconsistent policy outcomes of the two authorization procedures can be explained by exactly this difference of precaution employed by the actors.

Within the current EU framework governing the authorization for cultivation of GMOs it was not possible to find a compromise between the involved stakeholders.

What lessons can be drawn from this case study, regarding the regulation of GMOs in the EU? First and foremost, not the PP itself, but rather diverging thresholds for its use have caused undesirable regulatory results. Hence, it is questionable whether the Commission's proposal to disintegrate the decision-making process for the cultivation of GMOs is the only and best solution to this problem. It would only circumvent the issue at hand, instead of solving it. Moreover this would mean to sacrifice the benefits of regulation on a European level and possibly distort the internal market. Furthermore certain health and environmental risks connected to the use of GMOs transcend borders and therefore demand EU-wide solutions. Therefore, this paper has brought forward an alternative solution which keeps regulation on a European level, without compromising MS' capabilities of setting their own risk-thresholds. By requiring EFSA to develop FRADs, and by creating a process that is open to all stakeholders, the use of the PP can become more predictable and render the decision making process more effective. This can only be achieved by enhancing MS' trust in EFSA, as well as by a convergence of risk-thresholds. Furthermore, the review of all available scientific data would be guarded by strict procedural rules, making it easier for future authorizations to adhere to timelines.

In addition, recalling the more general criticism of the PP as an 'arbitrary', 'paralyzing', or 'non-science based' principle, one has to conclude that these features *can* be side-effects of the PP, yet the reasons for such results are to be found in the procedural application of the principle. Particularly in complex multi-actor, multi-level-governance frameworks such as the EU, it is very challenging to design a procedure that can reconcile all different perceptions of risk. Moreover, designing a procedural PP for the EU is especially difficult because it has to conform not only to national and European, but also to the international WTO legal framework.

Therefore, it is important for subsequent research to further develop a 'procedural PP', since traditional versions and interpretations of the PP can help explain the principle's shortcomings, yet provide little direction on how to solve its problems. The 'tool-box' provided by this paper addresses this deficit by providing a methodological framework that allows the researcher to analyze the PP in a procedural realm and address its flaws by designing practical changes which are to be integrated into the legal framework of a regulatory regime.

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